JUL 1 2013

510(k) SUMMARY

Submitted By: David Chadwick, Ph.D., RAC, FRAPS
Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402
Phone: (812)339-2235 Ex. 2330
Fax: (812)332-0281

Device:

Trade Name:	Cook Holmium Laser Fiber
Common Name:	Laser Fiber
Classification Name:	Laser Instrument, Surgical, Powered GEX (21 CFR §878.4810)

Indications for Use:

The Cook Holmium Laser Fiber is intended for incision/excision, ablation, and coagulation (hemostasis) when attached to the cleared H-30 Holmium Laser System for the indications for which the system has been cleared.

Predicate Device:

The Cook Holmium Laser Fiber is similar to the predicate device (OptiLite™ Holmium Laser Fibers; K073496) in terms of intended use, principles of operation, materials of construction, and technological characteristics.

Comparison to Predicate Device:

Cook Incorporated (formally Cook Urological, Inc.) currently markets the predicate OptiLite™ Holmium Laser Fiber cleared for marketing on January 23, 2008 (K073496). The similar indications for use, principles of operation, and technological characteristics of the Cook Holmium Laser Fibers as compared to the predicate device support a determination of substantial equivalence.

Device Description:

The Cook Holmium Laser Fiber is intended for incision/excision, ablation, and coagulation (hemostasis) when attached to the cleared H-30 Holmium Laser System for the indications for which the system has been cleared. The devices are supplied sterile in peel-open packages. The multi-use fibers have a color coded connector to identify the four different fiber sizes, and will be sold individually. The single-use fibers have a red connector and come in six sizes, and will be sold in boxes of three.

Test Data:

The proposed Cook Holmium Laser Fiber was subjected to the following tests to assure reliable design and performance under the specified testing parameters.

- Tensile Testing
- Bend Radius Testing
- Energy Loss Testing
- Accelerated Aged Testing
- Biocompatibility Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

July 1, 2013

Cook Incorporated
% Ms. Connie Rice, RAC
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K124030
Trade/Device Name: Cook Holmium Laser Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general surgery and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 11, 2013
Received: June 12, 2013

Dear Ms. Rice:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K124030

Device Name: Cook Holmium Laser Fiber

Indications for Use for the Cook Holmium Laser Fiber:

The Cook Holmium Laser Fiber is intended for incision/excision, ablation, and coagulation (hemostasis) when attached to the cleared H-30 Holmium Laser System for the indications for which the system has been cleared.

Prescription Use __XX__ OR Over-the-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Neil R Ogden
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(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K124030